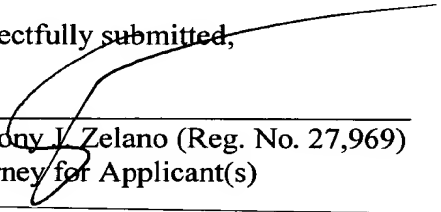


REMARKS

Claims 1-5 and 6-12 have been amended. Claim 6 has been canceled.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Respectfully submitted,



Anthony J. Zelano (Reg. No. 27,969)
Attorney for Applicant(s)

~~MILLEN, WHITE, ZELANO~~
~~& BRANIGAN, P.C.~~

Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Date: May 22, 2001

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claim 6 has been canceled.

Claims 1-5 and 7-12 have been amended as follows:

1. (Amended) A method of compensating for an absolute or relative testosterone deficiency with simultaneous prophylaxis for the development of a benign prostatic hyperplasia (BPH) or a prostate cancer comprising administering a Use of combination of preparations that contain a natural or synthetic androgen, and a component from the group of gestagens, an antigestagens, an antiestrogens, a GnRH analogs, a testosterone-5 α -reductase inhibitors, an α -andreno-receptor blockers or a phosphodiesterase inhibitors.

~~for compensating for an absolute or relative testosterone deficiency with simultaneous prophylaxis for the development of a benign prostatic hyperplasia (BPH) or a prostate cancer.~~

2. (Amended) A method Use of combination preparations according to claim 1, characterized in that wherein the natural androgen component is testosterone, ~~testosterone~~ testosterone undecanoate, dehydroepiandrosterone, dehydroepiandrosterone sulfate, testosterone propionate, testosterone enanthate, testosterone buciclate, testosterone cypionate or androstene dione.

3. (Amended) A method Use of combination preparations according to claim 1, wherein the synthetic androgen component is 17-methyltestosterone, fluoxymesterone, danazol, mesterolone, nandrolone decanoate, nandrolone phenylpropionate, oxandrolone, oxymetholone, or stanazolol.

4. (Amended) A method ~~Use of combination preparations~~ according to claim 1, wherein the gestagen component is dienogest, levonorgestrel, gestodene, desogestrel, norgestimate, norethisterone, a norethisterone ester acetate, levonorgestrel, or progesterone, chloromadinone acetate, cyproterone acetate, medroxy progesterone acetate, megestrol acetate, dydrogesterone, trimegestone or nomegestrol.

5. (Amended) A method ~~Use of combination preparations~~ according to claim 1, wherein the antigestagen component is

4-[17 β -Hydroxy-17 α -(methoxymethyl)-3-oxoestra-4,9-dien-11 β -yl]benzaldehyde-1(E)-oxime (J 912);

4-[17 β -methoxy-17 α -(methoxymethyl)-3-oxo-estra-4,9-dien-11 β -yl]-benzaldehyde-1(E)-{O-[(ethylthio)carbonyl]}-oxime (J 1042);

4-[9 α ,10 α -epoxy-17 β -hydroxy-17 α -(methoxymethyl)-3-oxo-estr-4-en-11 β -yl]-benzaldehyde-1(E)-oxime (J 1116);

4-[17 β -methoxy-17 α -(methoxymethyl)-3-oxoestra-4,9-dien-11 β -yl]benzaldehyde-1(E)-oxime (J 867);

4-[17 β -hydroxy-17 α -(methoxymethyl)-3-oxoestra-4,9-dien-11 β -yl]benzaldehyde-1(E)-{O-[(N-ethyl)-carbonyl]}-oxime (J 956);

11 β -[(4-N,N-dimethylamino)-phenyl]-17 β -hydroxy-17 α -propinyl-estra-4,9-dien-3-one (RU 38 486 - mifepristone);

11 β -[(4-N,N-dimethylamino)-phenyl]-17 α -hydroxy-17 β -(3-hydroxypropyl)-13 α -methyl-gona-4,9-dien-3-one (ZK 98299 - onapristone);

11 β -(4-acetylphenyl)-17 β -hydroxy-17 α -propinyl-estra-4,9-dien-3-one (ZK 112993);

11 β -[(4-N,N-dimethylamino)-phenyl]-17 β -hydroxy-17 α -(3-hydroxy-1-(Z)-propenyl)-estra-4,9-dien-3-one (ZK 98 734 - lilepristone);

11 β -[(4-N,N-dimethylamino)-phenyl]-17 β -hydroxy-17 α -(3-hydroxy-1-(Z)-propenyl)-estra-4-en-3-one (ZK 137 316);

11 β -[(4-N,N-dimethylamino)-phenyl]-6 β -methyl-4',5'dihydrospiro-[estra-4,9-diene-17,2'(3H)-furan]-3-one (ORG 31 710);

11 β -[(4-N,N-dimethylamino)-phenyl]-7 β -methyl-4',5'dihydrospiro-[estra-4,9-diene-17,2'(3H)-furan]-3-one (ORG 31 806); or

11 β -(4-acetylphenyl)-(3'E)-ethylidene-4',5'dihydrospiro-[estra-4,9-diene-17,2'(3H)-furan]-3-one (ORG 33 628).

7. (Amended) A method ~~Use of combination preparations~~ according to claim 1, wherein the GnRH-analog component is busarelin, goserelin, nafarelin, triptorelin or deslorelin, leuprolide or leuprolide acetate.

8. (Amended) A method ~~Use of combination preparations~~ according to claim 1, wherein the antiestrogen component is tamoxifen, raloxifene, panomifene, toremifene, iproxifene or idoxifene.

9. (Amended) A method ~~Use of combination preparations~~ according to claim 1, wherein the testosterone-5 α -reductase-inhibitor component is finasteride, epristeride, permixon, or turosteride.

10. (Amended) A method ~~Use of combination preparations~~ according to claim 1, wherein the α -andreno-receptor-blocker component is tolazoline, phentolamine, phenoxybenzamine, alfuzosin, or prazosin.

11. (Amended) A method ~~Use of combination preparations~~ according to claim 1, wherein the phosphodiesterase-inhibitor component is amrinone, milrinone, trapidil, papaverine, vesnarinone or sildenafil.

12. (Amended) A method of claim 1 ~~Use of a combination preparation according to at least one of claims 1 to 4~~, wherein said combination ~~it~~ is used in the form of a tablets, capsules, coated tablets, transdermal therapy systems, ampoules, suppositoryes, gels, ointments, nose drops, implants, pressed parts or biodegradable microspheres.

→ 112 / spelling